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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-13-13AHB]

Proposed Data Collections Submitted for

Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404-639-7570 or send comments to LeRoy Richardson, 1600 Clifton Road, MS-D74, Atlanta, GA 30333 or send an email to omb@cdc.gov.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d)

ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

Proposed Project

Risk Factors for Community-Associated *Clostridium difficile* Infection through the Emerging Infections Program (EIP)
- New – National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The epidemiology of *C. difficile* has changed dramatically during recent years, with increases in incidence and severity of disease being reported across several countries. In addition, populations previously thought to be at low risk, such as young, healthy individuals residing in the community, are now being identified with severe *C. difficile* infection (CDI). Community-associated CDI is estimated to represent 32% of all CDI based on population-based CDI surveillance data, with an incidence of 30-40 per 100,000 population in the United States. Previous reports

have shown that approximately 40% of patients acquiring community-associated CDI (CA-CDI) were not exposed to antibiotics, which is a well-recognized risk factor for CDI; suggesting that additional factors may contribute to infections. Other factors such as proton pump inhibitors have been raised as a risk factor for CDI in the community and on February 8, 2012, the U.S. Food and Drug Administration issued a communication advising physicians to consider the diagnosis of CDI among patients taking proton pump inhibitors. However, the data on the association of CDI with proton pump inhibitors are still controversial and studies to quantify this association are needed. In addition to the understanding of the factors that predispose patients to CDI, further evaluation of potential *C. difficile* exposure sources in the community is necessary to guide prevention efforts.

The sources of *C. difficile* and the risks for developing CDI in previously thought to be low-risk community populations are not well defined. Although initial evaluation of CA-CDI cases identified several potential risk factors (e.g., outpatient healthcare exposures, infants in the home, and proton pump inhibitor use), the magnitude of association of these risks with disease development using a control population has not been evaluated to date. This proposed case-control study will enable

investigators to evaluate these associations and focus future investigations and prevention strategies on those factors identified as significantly associated with disease development.

CDC requests OMB approval to collect information from the public using a standardized questionnaire over a three-year period. The study will have a pediatric and an adult component given that *C. difficile* exposure sources in the community may vary by age. For example, *C. difficile* has been isolated from daycare centers' environment which may be a potential source for *C. difficile* acquisition in pediatric population, but less likely to be a source for adults.

For this project, we estimate that 129 persons ≥ 18 years of age with *C. difficile* infection (case-patients) will be contacted for the CDI study interview annually. Of those, 71 will agree and be eligible to participate in the study and will proceed to the full telephone interview. A total of 142 persons ≥ 18 years of age without C*. difficile* infection (control-patients) will be contacted for the interview annually. Of those, 71 will agree and be eligible to participate in the study and will complete the full interview. Among the pediatric group, we estimate that 141 and 194 parents of children between 1 and 5 years of age with and without *C. difficile* infection will be contacted for

the interview, respectively. Among the case- and control-patients, we estimate that 78 in each group will agree and be eligible to participate in the study and will proceed to the full interview. We anticipate the screening questions to take about 5 minutes and the telephone interview 30 minutes per respondent in both the adult and pediatric groups.

There are no costs to respondents. The total response burden for the study is estimated as follows:

Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondent	Number of Responses per Respondent	Average Burden per Response	Total Burden (in hours)
Case Subjects ≤ 17 years of age (adult and pediatric)	Screening Process	141	1	5/60	12
	Telephone interview	78	1	30/60	39
Control Subjects ≤ 17 years of age	Screening Process	194	1	5/60	16
	Telephone interview	78	1	30/60	39
Case Subjects > 17 years of age	Screening Process	129	1	5/60	11
	Telephone interview	71	1	30/60	36
Control Subjects > 17 years of age	Screening Process	142	1	5/60	12
	Telephone interview	71	1	30/60	36
Total					261

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Office of the Associate Director for Science
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Centers for Disease Control and Prevention

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